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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,388	03/14/2001	Charbel Massaad	ST00010	3321

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 10/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,388

Applicant(s)

MASSAAD ET AL.

Examiner

Gerald Leffers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 6-22 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 11, mailed 7/8/02, is acknowledged. The traversal is on the ground(s) that 1) the groups of claims designated by the examiner fail to define inventions with properties that are so distinct as to warrant separate examination and search, 2) both of the groups have the same general classification and therefore require an identical search, 3) the examiner has admitted that the subject matter of the two groups is related, and 4) rejoining of the claims would not constitute an undue search burden for the examiner. This is not found persuasive because of the following reasons.

Applicants' response completely ignores the reasons provided by the examiner as to why the claims of the two different groups are drawn towards different and distinct inventions (e.g. product and process of use). Applicants' response does not question the validity of the asserted alternative use of the products of Group I. With regard to the same general classification, the fact that both groups reside in class 435 is not sufficient to show that the search burden for both groups is the same. In fact, the subclassification for the two groups is different, and this is all that is required to demonstrate an undue search burden on the part of the Office. With regard to the assertion that the subject matter of the two groups being related, the mere showing that two groups of claims are somehow "related" does not mean that the two groups can not be classified as different and distinct or that there is no undue search burden for the Office to examine both groups of claims together in the same application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 23-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Information Disclosure Statement

Receipt is acknowledged of an information disclosure statement filed 7/11/01 as Paper No. 3. The signed and initialed PTO Form 1449 has been mailed with this action.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It was not executed in accordance with either 37 CFR 1.66 or 1.68 (i.e. the signature of Jean-Luc Olivier has not been dated).

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the details of the invention as described in the specification. For example, Figures 1 and 4 are so illegible as to make any attempt to interpret their meaning impossible. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected

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drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 6-20 and 25 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiply dependent claim. See MPEP § 608.01(n). **Accordingly, claims 6-20 and 25 have not been further treated on the merits.**

Claims 1-5 and 21-22 are objected to because of the following informalities: the claims lack the words “A” or “The” at the beginning of the claim. Appropriate correction is required.

Claim 22 is objected to because of the following informalities: it lacks the word “of” between the words “sequence” and “SEQ”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Each of the claims comprises the limitation that the claimed hybrid promoter comprises “part” of the promoter for the PLA2s gene. The specification does not make clear the boundaries for what constitutes the “whole” PLA2s promoter, or for “part” of the promoter (see below). Thus, each of the rejected claims encompasses embodiments where only a single nucleotide is present from the PLA2s promoter. Since PPARs are involved in transcriptional regulation of a number of different genes, the rejected claims encompass a huge genus of promoters where any PPAR element is operatively linked to any promoter. Claims 3-5 further comprise the limitation of a “functional variant” of a given PPAR-binding sequence (e.g. SEQ ID NOS: 1-4). SEQ ID NOS: 1-4 describe variants of the DR1 PPAR-binding sequence.

With regard to a hybrid promoter comprising only a “part” of the PLA2s promoter as well as a PPAR-binding element, there is insufficient structural/functional basis in the specification or prior art to envision a sufficient number of representative embodiments embraced by the rejected claims to describe the broadly claimed genus of hybrid promoters. Therefore, one of skill in the art would have reasonably concluded applicants were not in possession of the claimed invention.

With regard to the limitation of a “functional variant” of one of the PPAR-binding sequences recited in claims 3-5, even for the shortest of the sequences, SEQ ID NO: 1, the number of nucleotides in the sequence is large enough to generate a tremendous number of alternatives that must retain functional PPAR-binding activity (i.e. SEQ ID NO: 1 comprises 20 nucleotides, or 2^5 possible variants). The specification does not make clear those nucleotide

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positions within any of the recited sequences that are essential for PPAR-binding activity. The prior art of record does not appear to offset the deficiencies of the instant specification with regard to providing a structural/functional basis for one of skill in the art to envision a sufficient number of "functional variants" of the recited sequences to describe the broadly claimed genus. Therefore, one of skill in the art would reasonably conclude that applicants were not in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the words "hybrid promoter" are unclear. Does the term refer to any promoter having a PPAR element and at least part of the PLA2s promoter? Or does the phrase refer to a recombinant promoter comprising a PPAR element and a heterologous sequence from the PLA2s promoter that is not normally associated with that particular PPAR element?

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "...the whole or part of the promoter of the PLA2s gene..." are unclear. The specification and prior art do not appear to put limits on what constitutes the "whole" PLA2s promoter or what constitutes "part" of the PLA2s promoter. Exactly what are the nucleotide boundaries of the whole PLA2s promoter? Alternatively, would a single nucleotide from within the PLA2s promoter constitute a

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“part” of the promoter? It would be remedial to amend the claim language to set precise nucleotide boundaries for the PLA2s promoter.

Claim 2 is vague and indefinite in that it is unclear as the claim is written how the phrase “...characterized in that the PPAR response element (a) comprises one or more PPAR-binding sites...” further limits the hybrid promoter of claim 1, if at all. Upon reading the specification, it appears that a PPAR response element (i.e. PPRE) necessarily comprises at least one PPAR-binding site. It would be remedial to amend the claim language to more explicitly limit claim 1.

Claims 3-4 are vague and indefinite in that the metes and bounds of the term “functional variants” are unclear. It is unclear upon reading the specification what is the minimum number and type of nucleotides that must be retained in order for a given sequence to be a “functional variant” of one of the recited sequences. It would be remedial to amend the claim language to clearly indicate what minimal sequences from the recited sequences must be retained in order for a nucleic acid comprising the sequence to meet the claim limitation of being a “functional variant”.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Couturier et al (J. Biol. Chemistry, August 1999, Vol. 274, No. 33, pages 23085-23093; see the entire document).

Couturier et al describe the characterization of the PLA2s gene and those elements that are responsible for regulating transcription of the gene. Couturier et al demonstrate that the rat^{pp2} PLA2s promoter comprises at least one PPAR-binding element with extensive homology with a known PPAR-binding element (e.g. DR1) (e.g. page 23090, column 2, 4th paragraph; Figure 9).

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al (U.S. Patent No. 6,413,994).

Evans et al teach the use of PPAR γ -binding elements operatively linked to a reporter gene under control of the thymidine kinase promoter in order to identify compounds that modulate the activity of PPAR γ (e.g. the Abstract, Example 2). The TK promoter would necessarily comprise at least one nucleotide from the PLA2s promoter (i.e. a "part" of the PLA2s promoter) operatively linked to at least one copy of a "functional variant" of a PPAR-binding element.

Conclusion

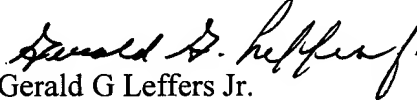
No claims are allowed. Claims 6-22 and 25 are objected to as being improperly multiply dependent and/or lacking an article to start the claim. Claims 21-22 are free of the art. Claims 1-5 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gerald G Leffers Jr.
Examiner
Art Unit 1636

ggl
September 30, 2002